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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,853	01/15/2004	Patrick E. Guire	9896.141.3.1	8747

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EXAMINER	
BOYKIN, TERRESSA M	
ART UNIT	**PAPER NUMBER**
1711	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/759,853	GUIRE ET AL.	
	Examiner	Art Unit	
	Terressa M. Boykin	1711	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *10-18-06*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29,32,34,43,45,46,48 and 49* is/are rejected.

7)☒ Claim(s) *30,31,33,35-42,44,47 and 50* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 January 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Arguments

Applicant's arguments filed 7-24-6; 10-18-6 have been fully considered and appreciated but they are not persuasive. However, in view of further consideration, additional claims appear to be anticipated by the reference. The new rejection appears as follows:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 29,32,34,43,45,46,48, 49 are rejected under 35 U.S.C. 102(e) as being anticipated by

Applicants argue:

> Zhong does not anticipate claims 29 or 46. "A claim is anticipated *only* if *each and every* element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference" *Verdegal Bros. v. Union Oil Co. of California,* 814 F.2d 628, 631 (Fed. Cir. 1987) emphasis added.

The Examiner would like to direct the applicants attention to the reference, which, not unlike applicant's specification, is directed to a surface treatment or coating for a medical device

Contrary to applicants arguments, applicants claim do not in themselves limit the coating to a thin or ultra thin layer; even the term monolayer does not necessarily limit the thickness.

Note further that both the reference and the specification employ a hydrophilic surface (or substrate) coating to the same support (polyesters, polyurethanes, glass and metals.

Further, both the reference and applicants specification contain latent or (reactive groups upon or dissaffinitive or repellent groups) when activated or when coming in contact with a particular moiety (i.e. reference, bacteria) or nonspecific attraction.

With regard to the limitation of "photoreactive groups, which are covalently bound to each other or to the surface" note that - diazirines are mentioned in both applicants specification on page 21 and importantly in the reference in col. 7 line 57.

With regard to applicants claim 29 regarding a coated medical device comprising a medical device including one or more surfaces coating a coating formed from composition including self-assembling monolayer molecules covalently adjoined to one or more surfaces with one or more latent reactive groups., Note that the reference discloses a method of providing a self-assembling monolayer on a surface, the method comprising the steps of: a) providing on the surface both latent reactive groups and a monolayer formed of self-assembling monolayer molecules, and b) activating the latent reactive groups under conditions suitable to either covalently attach the self-assembled monolayer to the surface and/or to form a stable monolayer film on the surface, by initiating polymerization of suitable groups provided by self-assembling monolayer molecules themselves and/or by forming intermolecular bonds between the self-assembling monolayer molecules.

Note that the applicants recited "self assembling' is interpreted by the Examiner as a layer or coating that is chemically or physically adhered to another layer which itself aligns coats.

The Examiner interpretation of the recited "monolayer' while remaining within the scope of the specification as defined by applicants is " film or layer one molecule thick formed at the interface between water and either oil or air by a substance such as a partially esterified fatty acid that contains both hydrophobic and hydrophilic groups in the same molecule."

With regard to claims 32 wherein the surface is provided by a material selected from ceramics, metals and polymeric materials.

With regard to claim 34 wherein the material comprises a polymeric material selected from the group consisting of polystyrene, polycarbonate, polyester, polyethylene, polyethylene terephthalate (PET), polyglycolic acid (PGA), polyolefin, poly-(p-phenyleneterephthalamide), polyphosphazene, polypropylene, polytetrafluoroethylene, polyurethane, polyvinyl chloride, polyacrylate (including polymethacrylate), and silicone elastomers, as well as copolymers and combinations thereof.

With regard to claim 43 wherein the medical device is implanting the surface into a body to provide a passivating effect. Note the reference states

With regard to claim 46 wherein the coated medical device, note that

With regard to claims 45 and 48 wherein the monolayer forming molecule have themselves been provided with latent reactive groups note that the Examiner interpretation of the recited "latent" while remaining within the scope of the specification as defined by applicants is "present or potential but not evident or active".

With regard to claim 49 wherein the latent reactive groups comprise photoreactive aryl ketones attached to the hydrophilic domains.

The reference provides an implantable medical device having a substrate with a hydrophilic coating composition to limit in vivo colonization of bacteria and fungi. The hydrophilic coating composition includes a hydrophilic polymer with a molecular weight in the range from about 100,000 to about 15 million selected from copolymers acrylic acid, methacrylic acid, isocrotonic acid and combinations thereof.

The reference more specifically discloses a substrate, e.g. medical device such as angioplasty balloon, with lubricous, hydrophilic coating includes coating

the substrate with a first aqueous coating composition comprising an aqueous dispersion or emulsion of first polymer having organic acid functional groups and first polyfunctional crosslinking agent having functional groups capable of reacting with the organic acid groups, and drying the first coating composition to obtain a water-insoluble coating layer including functional groups reactive with organic acid groups; and contacting the dried coating layer with a second aqueous coating composition comprising an aqueous solution or dispersion of hydrophilic polymer having organic acid functional groups, second polymer having organic acid functional groups, and second polyfunctional crosslinking agent having functional groups capable of reacting with organic acid groups, and drying to effect covalent bonding of hydrophilic polymer and second polymer to the first polymer through the first or second crosslinking agent to form a hydrophilic coating. The first and second polymers may be the same or different. The first and second crosslinking agents may be the same or different.

The above may be used for providing a substrate, e.g. medical device such as angioplasty balloon (claimed), catheter, or guide wire, with hydrophilic coating which becomes lubricous when contacted with aqueous fluid, thus, making it possible to coat devices which are sensitive to high processing temperature such as polyethylene terephthalate balloon catheter.

In view of the above, the reference appears to anticipate that claimed invention with regard to 'each and every element". Consequently, the claimed invention cannot be deemed as novel and accordingly is unpatentable.

Correspondence

Please note that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources. Applicants may be referred to the Electronic Business Center (EBC) at http://www.uspto.gov/ebc/index.html or 1-866-217-9197.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Terressa Boykin whose telephone number is 571 272-1069. The examiner can normally be reached on Monday through Friday from 6:30am to 3:00pm.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

tmb

Examiner Terressa Boykin

TERRESSA M. BOYKIN
PRIMARY EXAMINER